

REMARKS

This submission is in response to the Official Action dated September 21, 2006. Claims 58, 60, 62-71, 89, 91-94, and 96 -124 are currently pending. Claims 58, 89, 92- 93, 96, and 98 are amended herewith. Reconsideration of the above-identified application, in view of the following remarks, is respectfully requested. Each of the Examiner's rejections is discussed below.

Rejection under 35 U.S.C. §112

The Examiner has rejected claims 58, 89, 92- 93, 96, and 98 for incorporating new matter. Particularly, the Examiner states that the phrase "or can be rendered substantially water-insoluble by chemical reaction with an alkali halide," while supported for silver nitrate, is not supported for rendering all antimicrobial metallic materials in general substantially water insoluble.

Applicants respectfully traverse. However, applicants amend claims 58, 89, 92- 93, 96, and 98 herewith, removing the phrase "by chemical reaction with an alkali halide" in order to expedite allowance of the claims. The removal of this phrase will not broaden the present claims such that they are anticipated by U.S. Patent No. 5,681,802 to Fujiwara. As stated in the Response to Official Action dated February 27, 2006, the alkali or alkaline earth metal salts described by Fujiwara, (i.e., NaCl, Na sulfonate, and potassium sorbate) are all soluble in water; Fujiwara discloses neither the use of water insoluble metallic materials nor any reaction that would make the Fujiwara salts insoluble.

Rejection under 35 U.S.C. §103

Claims 58, 60, 62-64, 68-71, 89, 92, 93, 96, 98-103, 105-106, 108-114, and 117-124 have been rejected as obvious over WO 97/00076 to Morlet in view of Fox (U.S. Pat. 5,374,432) and further in view of Smith (U.S. Pat. 5,576,006). The Examiner states that Morlet teaches compositions containing biguanide polymer in topical treatments of microbial infection and further teaches the use of carriers. While the Examiner admits that Morlet teaches neither antimicrobial metallic materials nor moisture resistant films, she states that Morlet does teach compositions

having further pharmaceutically active substances such as antimicrobials. The Examiner contends that Morlet can be combined with Fox which teaches a topical composition having an antimicrobial metal and an antibiotic. The Examiner also contends that Morlet can be combined with Smith, which teaches forming antimicrobial compositions, including biguanides, having a higher molecular weight that are more resistant to being washed away.

Applicants respectfully traverse. Contrary to the Examiner's statement, there is no motivation to combine Morlet with Fox and/or Smith in such a way to obtain the currently claimed invention. There is nothing in Morlet to suggest the need for dermal antiseptic formulations exhibiting persistent efficacy and microbial barrier properties as described in the present claims (see para. 8). The presently claimed invention teaches not only that there was a problem that needed to be solved, but also that there was a way to solve it. *In re Zurko* 111 F.3d 887 (Fed. Cir. 1997).

While Morlet does suggest adding a carrier (see pg. 10), this teaching is in no way sufficient to suggest the formation of a moisture-resistant film on the skin which imparts a persistent antimicrobial activity. The composition in Morlet are taught as useful for treating microbial infections and as an antiseptic, "which is used for disinfecting, i.e., cleaning or sterilizing, rather than for treatment of infection." (See Morlet pg 4 line 17 – 31). These activities have short term effect; there is no suggestion in this discussion or elsewhere in Morlet that there is even a need for persistent antimicrobial activity as provided in the presently pending claims. It is error to reconstruct the presently claimed invention using the claims as a blueprint. There must be some reason for a combination which provides persistent antimicrobial activity other than hindsight. *Interconnect Planning Corp. v. Feil* 774 F.2d 12 (Fed. Cir. 1985). Since Morlet never considered the need for persistent films, he provides no motivation to modify his composition to create the compound forming a persistent film as in the present claims.

Although Morlet teaches the additional of antimicrobial agents including a polypeptide (bacitacin) or a compound useful as an eye drop (trimethoprin) (see pg. 10), this teaching is in no way sufficient to suggest the addition of a metallic metal material to a biguanide polymer. There is nothing in Morlet to suggest the addition of a metallic material as opposed to any other agent. In

addition to a teaching or suggestion to combine, there must be some reasonable expectation of success found in the prior art. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

Further, Morlet's statement that additional agents may be added to the formulation is not sufficient to direct a person of ordinary skill in the art at the time of the invention to combine a formulation within the teachings of Morlet with either Fox or Smith. There is nothing to teach or suggest a reasonable expectation of success in forming a composition that solves the problem as disclosed in the present invention to provide a moisture-resistant film having persistent antimicrobial efficacy.

Similarly, Fox lacks a motivation to combine the teachings of Fox with the teachings of Morlet. Fox teaches an anti-infective composition containing silver or a silver salt. There is nothing in Fox to suggest combining the metal-containing anti-infective composition with a biguanide polymer such as to form a moisture-resistant film on the skin.

Smith also provides no motivation to combine the high molecular weight antimicrobial compounds with an antimicrobial metallic material. Smith teaches that an odor absorber, neutralizer, or perfume may be used in the complex (col. 3, lines 31 – 37). There is no suggestion to combine this complex with an antimicrobial metal material. Smith teaches that his composition is effective and has a lasting effect (see col. 3, line 21-25). It is therefore counterintuitive to consider the need to add an additional antimicrobial agent such as a metallic material.

There must be some teaching, suggestion, or motivation to combine the references in an obviousness argument (*C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1351 (Fed. Cir. 1998)). It is impermissible to "pick and choose among the individual elements of assorted prior art references to recreate the claimed invention." *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.* 859 F.2d 878 (Fed Cir. 1988). Since there is no such teaching, claims 58, 60, 62-64, 68-71, 89, 92, 93, 96, 98-103, 105-106, 108-114, and 117-124 are not obvious over Morlet in view of Fox and Smith. Therefore, Applicants therefore request that this rejection be withdrawn.

Claims 65-67, 91, 94, 97, 104, 107, and 115 – 116 are rejected as obvious over Morlet in view of Fox, Smith, and further in view of WO 95/17152 (the '152 publication). The Examiner contends that, while Morlet, Fox, and Smith do not teach forming an adduct with methylene-bis-N,N-diglycidylaniline, the '152 publication does, and it would be obvious to combine this compound, the silver iodide also taught in the '152 publication, and the composition taught by the combination of Morlet, Fox, and Smith. The Examiner additionally states WO '152 teach the antimicrobial compositions are safe for application to the body.

Applicants respectfully traverse. As discussed above, there is no motivation to combine Morlet with Fox and Smith. There is similarly no motivation to combine these references with an additional reference (WO '152).

Further, Applicants contend that the Examiner has mischaracterized the ‘152 publication. WO ‘152 teaches that the solutions described therein preferably do not contain antimicrobials. WO ‘152 provides a liquid dispensers having a non-leachably attached antimicrobial coating, and teaches that this dispenser may be filled with a solution, such as a preservative-free sterile eye care liquid (‘152 page 6 and 27). The fact that WO ‘152 exemplifies a liquid that may be used in the dispenser does not teach or suggest that that liquid is antibacterial, or that that liquid contains any of the dispenser coating components. WO ‘152 teaches how to substantially reduce the amount of dissolved silver (an antimicrobial) in the solution by passivating the silver-coated surface (pg 22 lines 23 – 25). Therefore, there is no suggestion to combine the liquid dispensers which can be filled with preservative free solutions with Morlet, Fox, and Smith to apply an antimicrobial film on the skin.

Contrary to the Examiner's comment, WO '152 does not teach "antimicrobial compositions are suitable for sterilizing solutions such as eyecare liquids" and thus safe for application to the body. In fact, compositions in WO '152 are not suitable for use on the skin; many of these formulations use epoxy chemistry for forming the films on liquid dispensers. People often have

sensitivity to epoxides, with adverse reactions upon contact with the skin. Therefore, these compounds are not suitable for topical use. Example 19 does not disclose silver iodide; Example 18(c) provides silver iodide, however, the metal salt is provided in a solution containing DMF, a readily absorbable solvent which is harmful and can be fatal if adsorbed through the skin. This solution is not safe for use with compositions meant for application to the body.

Since WO '152 both teaches away from putting antimicrobials into solution and provides compositions that cannot be applied to the skin, a person of ordinary skill in the art, upon reading WO '152, would not be motivated to combine the teachings with Morlet, Fox, and Smith to produce a composition comprising the biguanide polymer present as an adduct with a substantially water-insoluble organic compound such as methylene-bis-N,N-diglycidylaniline, an antimicrobial metallic material, and a carrier.

Therefore, applicants respectfully request that the rejection under 35 U.S.C. §103 for claims 58, 60, 62-71, 89, 91-94, and 96-124

Double-Patenting

All claims have been rejected by the Examiner under the judicially created doctrine of obviousness-type double-patenting as being allegedly unpatentable over various claims in commonly-owned U.S. Patents 6,180,584; 6,030,632; 5,869,072; and 5,817,325. Upon indication of allowable subject matter in the present application, the allowable subject matter not being patentably distinct from the claims of one or more of the above-cited patents, an appropriate terminal disclaimer will be timely filed.

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Therefore, in view of the above remarks, it is earnestly requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining that the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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